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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,001	10/21/2005	Mark T Bilodeau	21299YP	1872
210 7590 04/09/2009 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
EXAMINER				
CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
04/09/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/554,001

**Applicant(s)**

BILODEAU ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 11 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 11 and 13-16 is/are allowed.
- 6) ☒ Claim(s) 17-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated Jan. 29, 2009 have been entered and considered carefully.

A terminal disclaimer was filed by applicants and was acceptable.

An error is hereby corrected for the previous office action. The elected invention is group IV. Therefore, claims 11, 13-14 and claims 1-7, 15-18 reading on the elected compounds are prosecuted. Claim 8 is removed from the rejections. Claims 1-6, 15-18 were rejected under 35 USC 103(a) and obviousness type double patenting over US 7,141,055 in view of US7,304,063. Claims 11, 13-14 are objected to for being dependent on the rejected base claims.

Claims 7-10, 12 and 19-20 have been canceled. Claims 1-6, 11, 13-18 are pending.

2. By amending the scope of claims 1-6, 15-18 to the elected scope wherein Q is explicitly pyrimidinylpyrazole, claims 1-6, 11, 13-16 would be allowable.

Claims 17-18 are subject to the following new grounds of rejection.

3. Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds of formula A wherein Q is pyrimidinylpyrazole in treating carcinoma, does not reasonably provide enablement for treating the scope of cancers of the claims encompassing any and all cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims.

Cancer treatment is a highly unpredictable field of endeavor. It is conventionally recognized that five class of cancer can be identified histologically. Within each class similarity in cancer cells may be observed (see cancer classification attached). It is further evidenced that according to National Cancer Institute, for a compound to be qualified as broad spectrum anti-proliferation agent, a multiple cell penal test must be provided (see Grever et al.).

The specification provided testing results that the compounds are effective against exclusively carcinoma (please note that MCF7, LnCaP, PC3, C33a, OVCAR-3, MDA-MB-468 disclosed on page 78 are all carcinoma cell lines) but lacks sufficient information on anti-cancer

against multiple class of cancerous tissue. In view of the multiple cell penal test guidelines in qualifying for broad general antiproliferation compounds, support for the scope of the claims are limited to carcinoma (see ATCC description).

4. Applicants amendment necessitated the new grounds of rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Apr. 6, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*